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(54) **SUTURELESS ANCHORING DEVICE FOR CARDIAC VALVE PROSTHESES**

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(57) **ABSTRACT**

A device for anchoring a prosthetic heart valve on biological tissue, includes first and second anchoring assemblies, mutually couplable to secure biological tissue therebetween. The anchoring assemblies include at least one pair of complementary arched portions having anchoring formations for anchoring on the biological tissue. The anchoring formations include integral extensions of the anchoring assemblies extending radially outwardly of one of the anchoring assemblies.

16 Claims, 15 Drawing Sheets

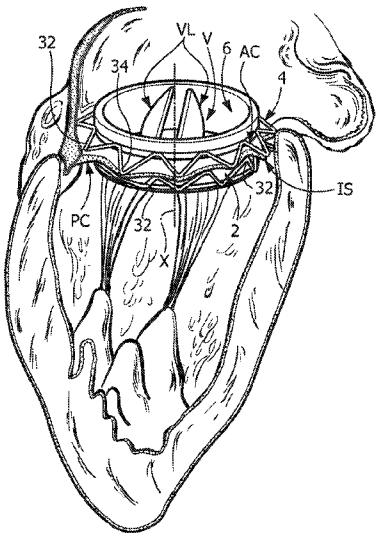

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FIG. 1A

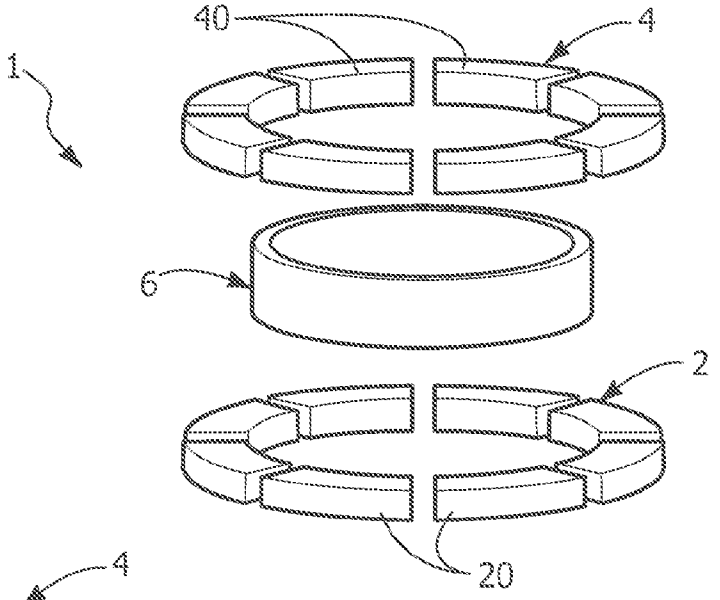


FIG. 1B

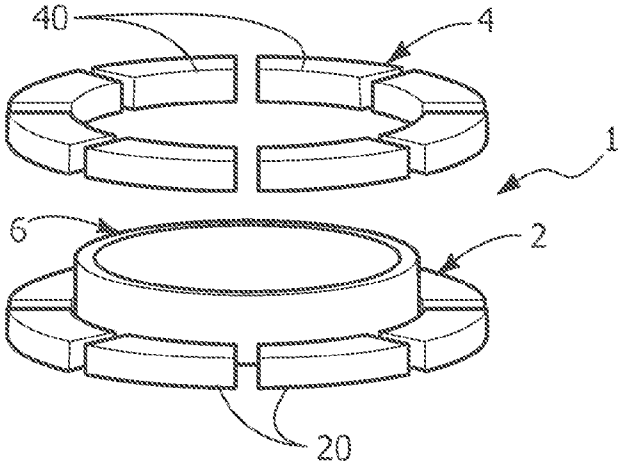


FIG. 1C

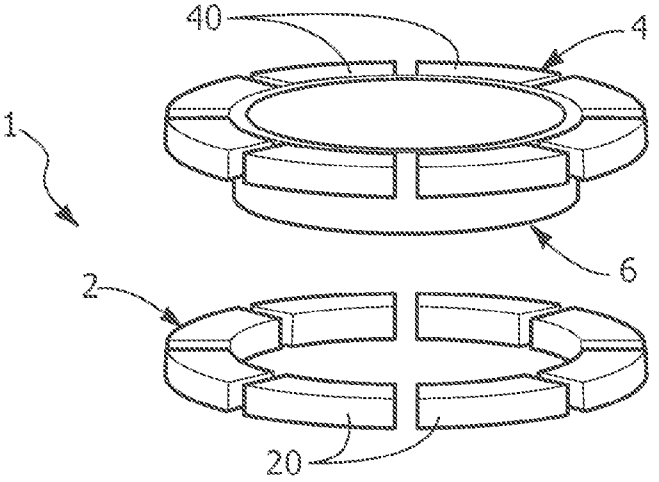


FIG. 2A

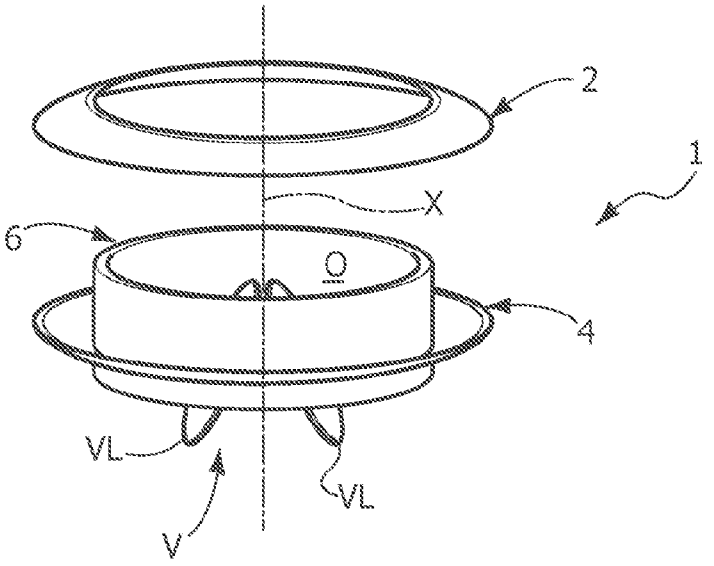


FIG. 2B

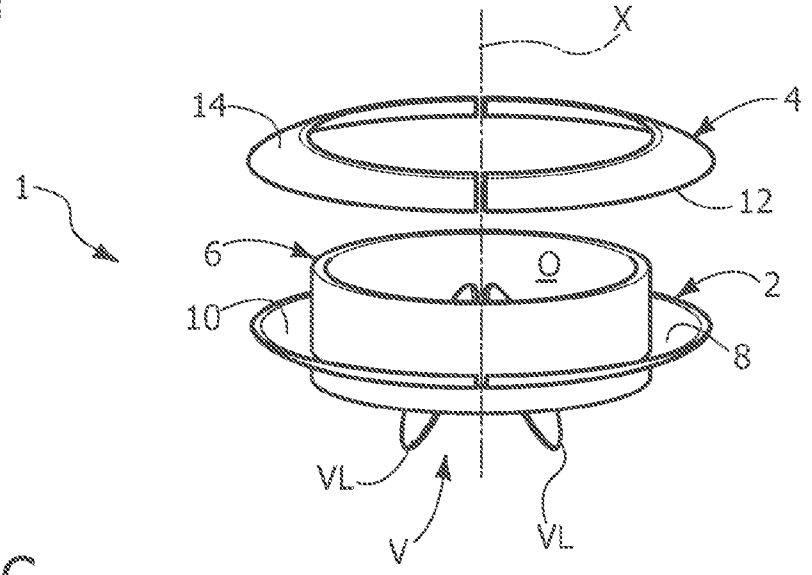


FIG. 2C

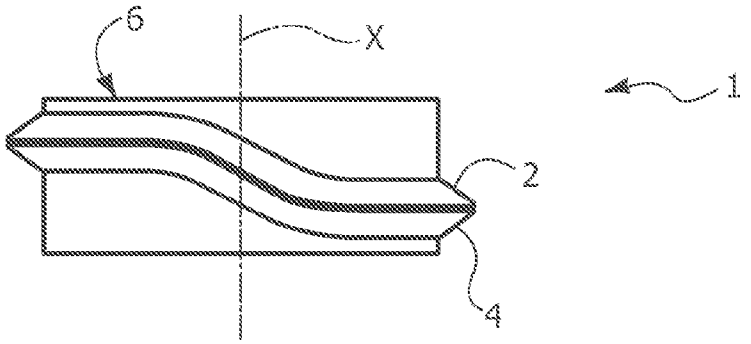


FIG. 2D

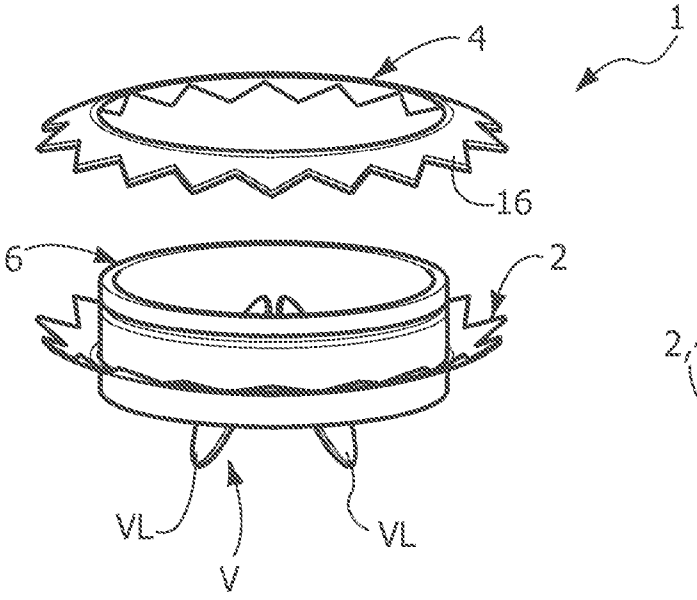
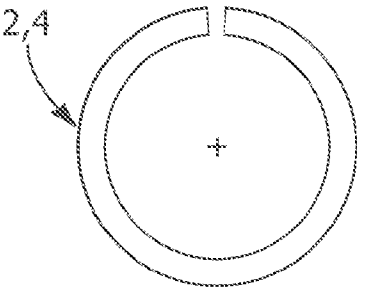


FIG. 3A



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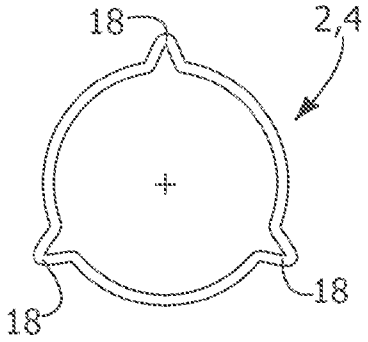


FIG. 3C

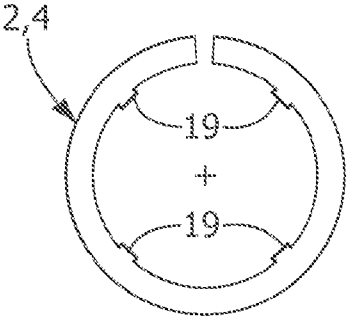
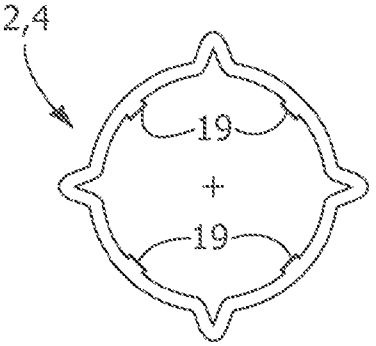


FIG. 3D



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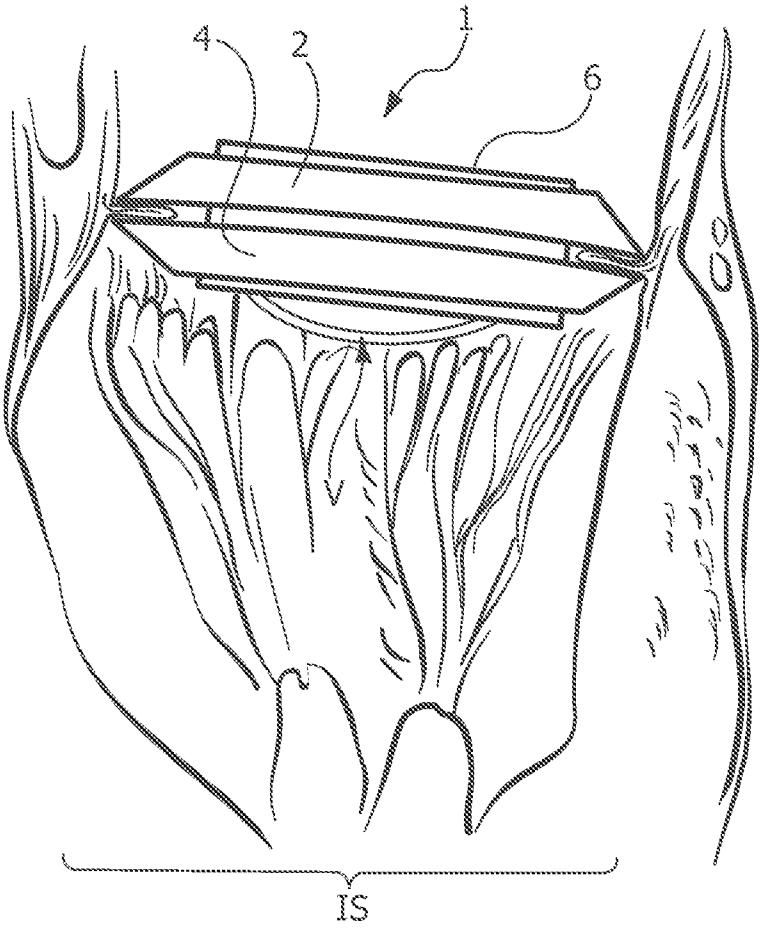


FIG. 5A

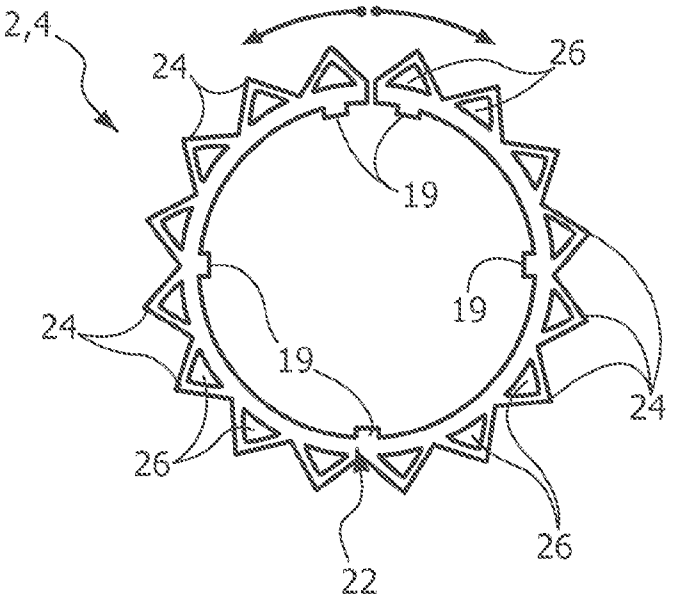


FIG. 5B

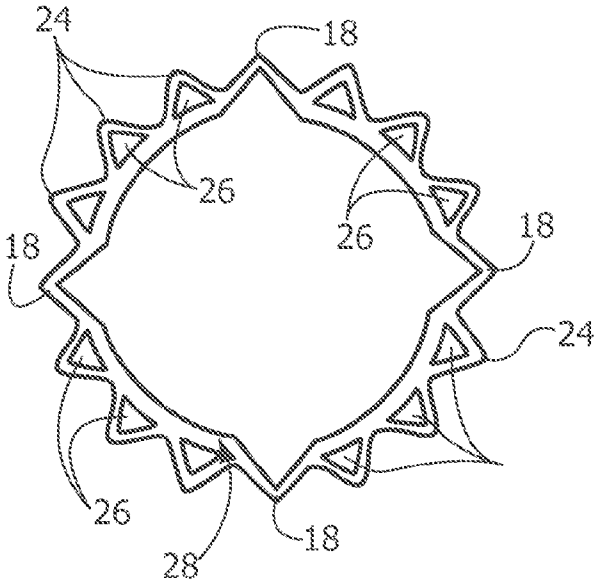
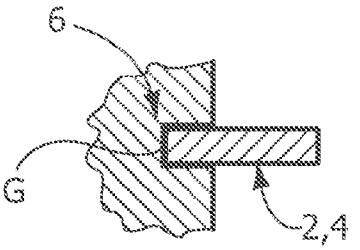


FIG. 6



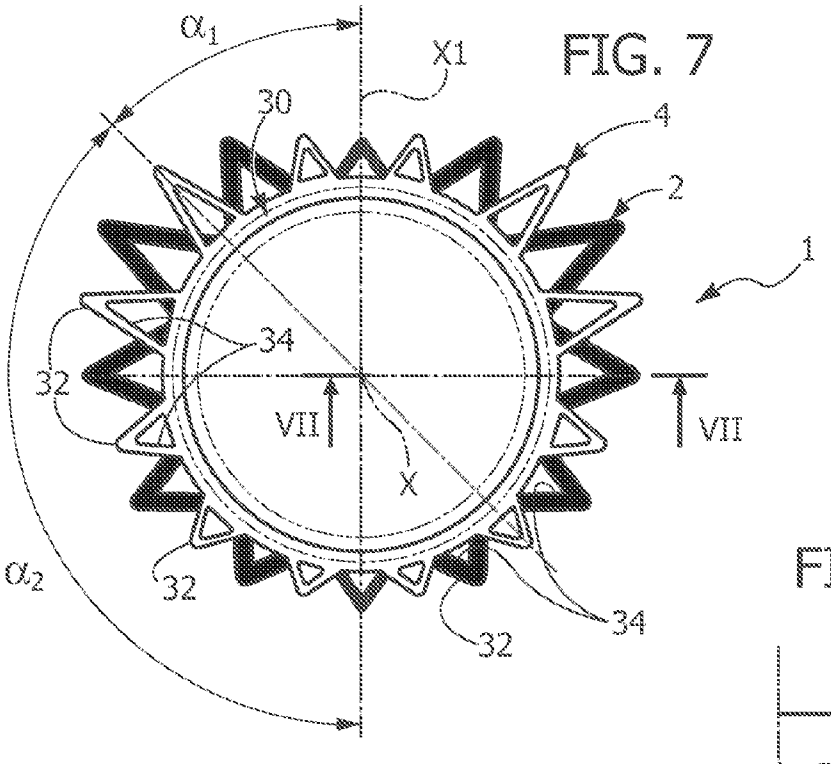


FIG. 7

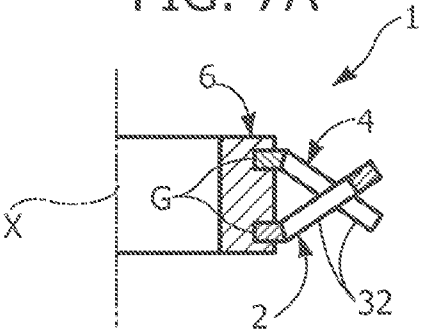


FIG. 7A

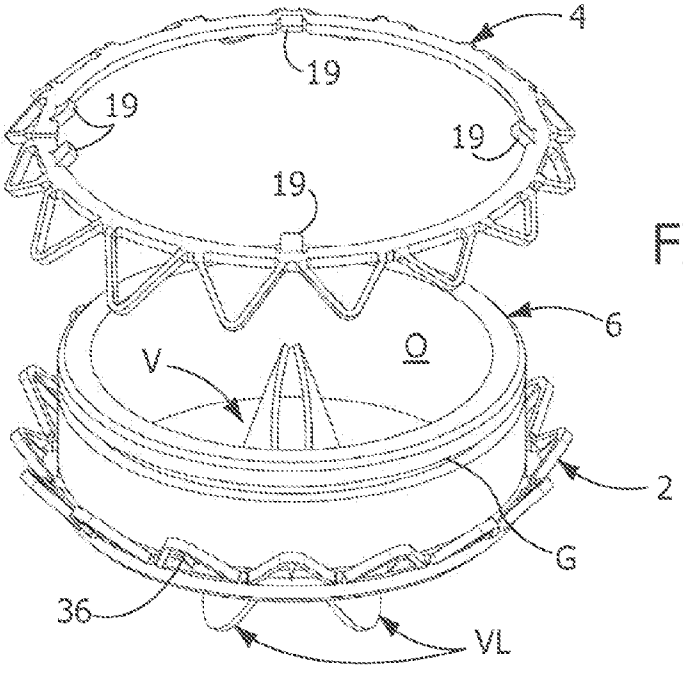


FIG. 8A

FIG. 8B

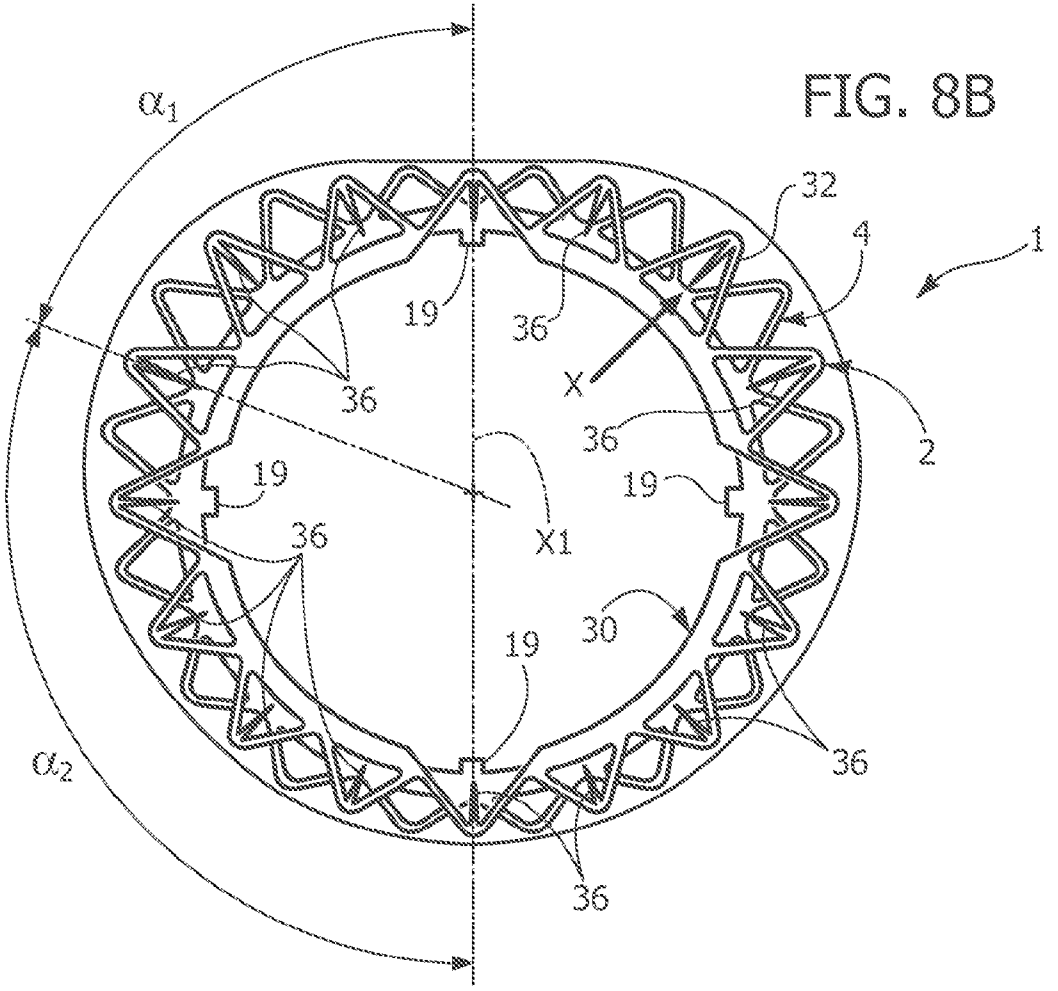
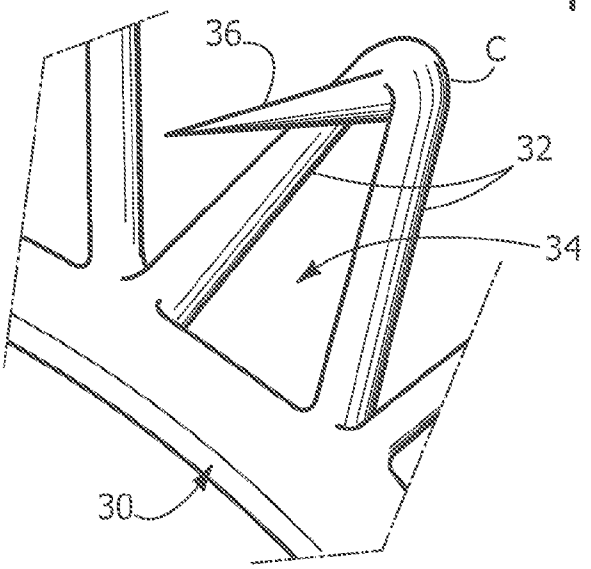


FIG. 10A



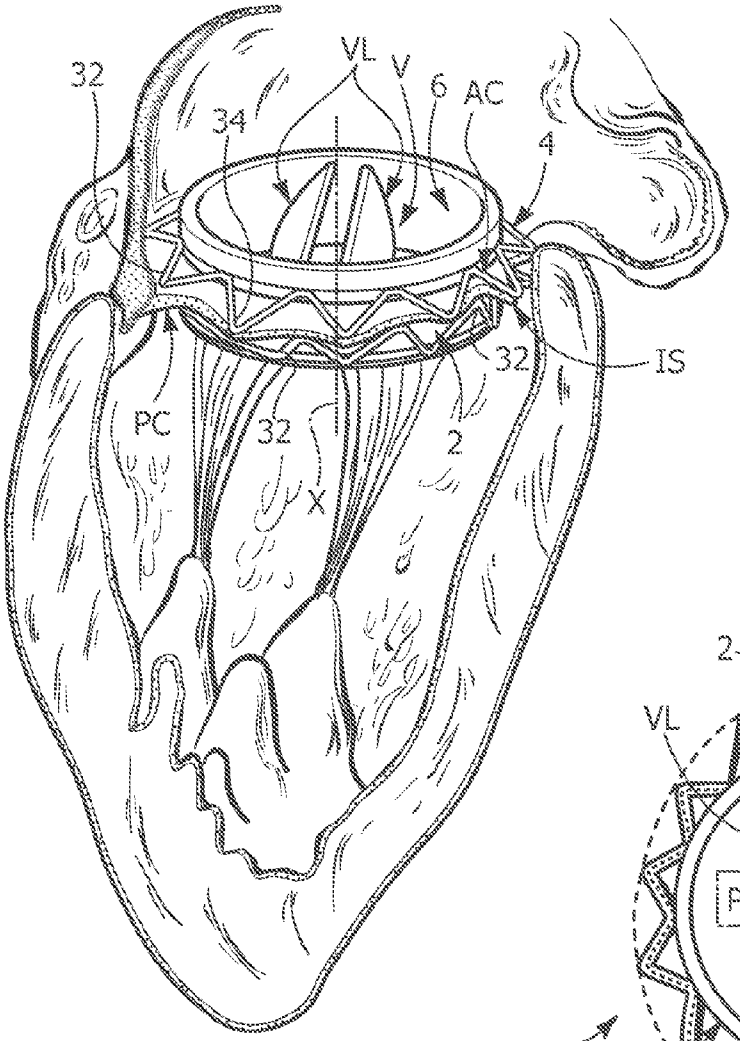
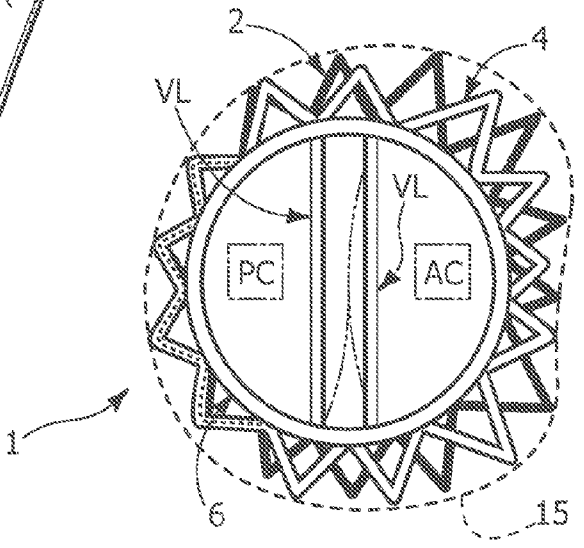


FIG. 9A

FIG. 9B



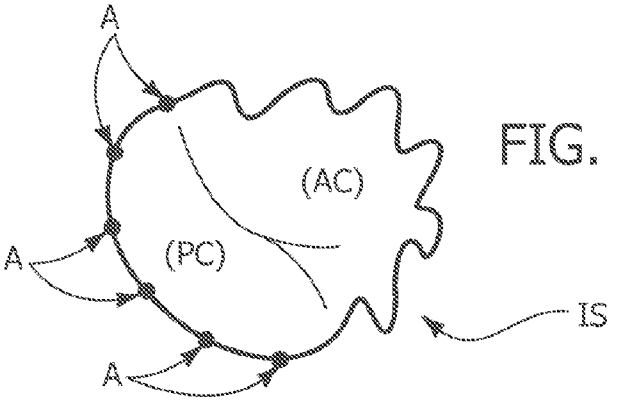


FIG. 9C

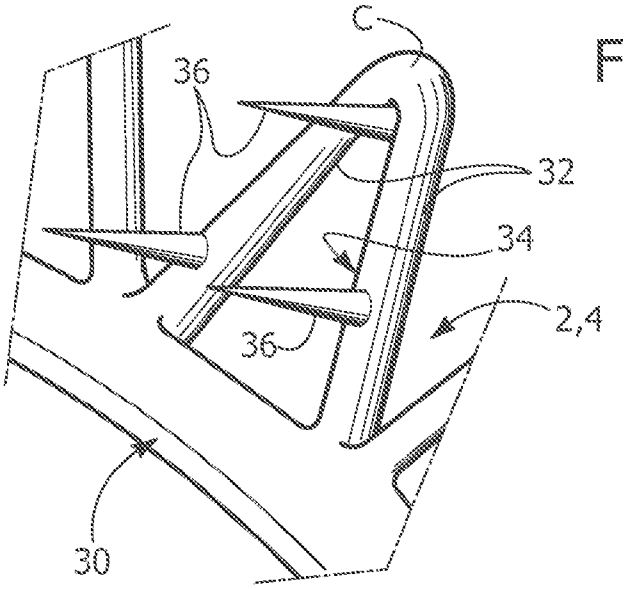


FIG. 10B

FIG. 10C

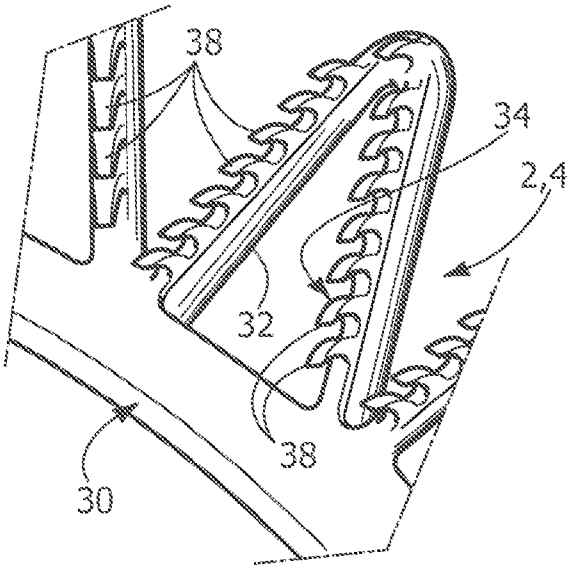
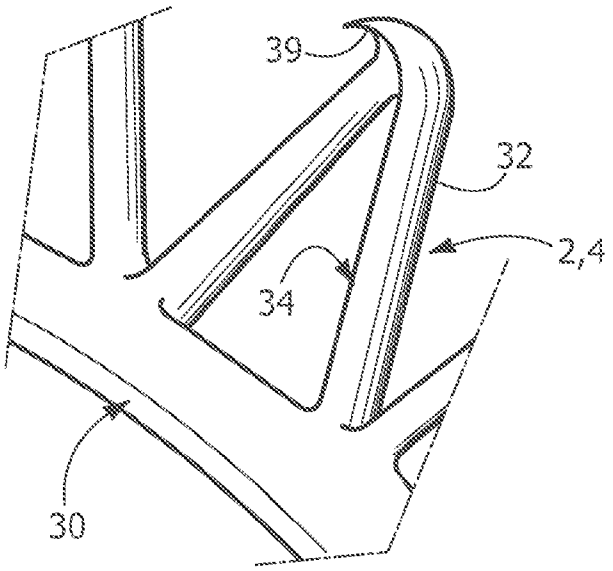


FIG. 10D



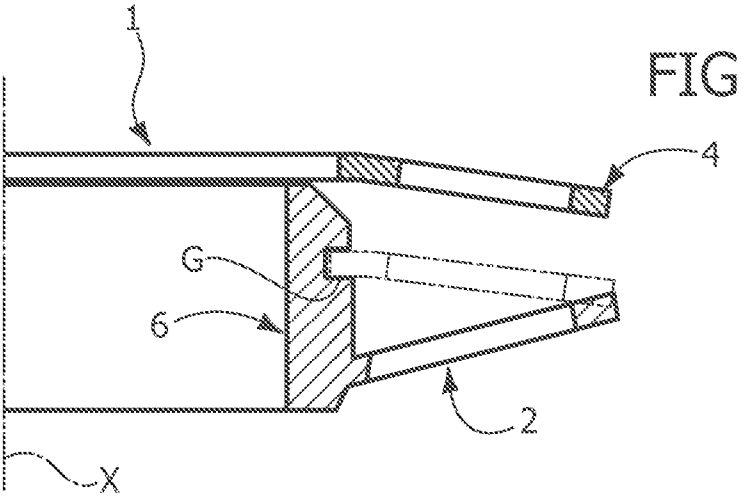


FIG. 11A

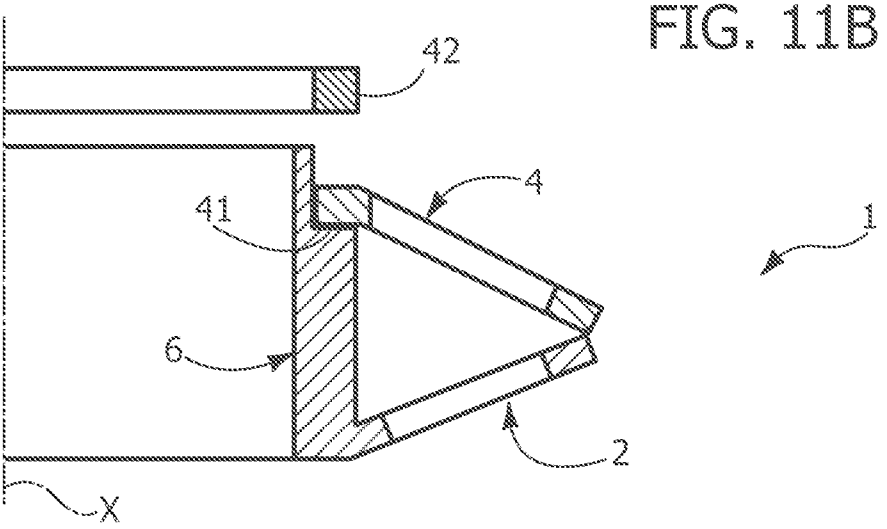


FIG. 11B

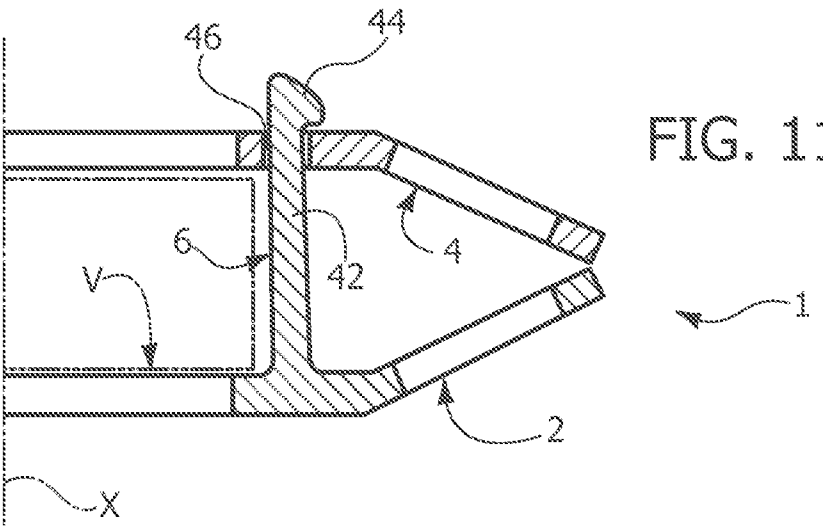


FIG. 11C

FIG. 12A

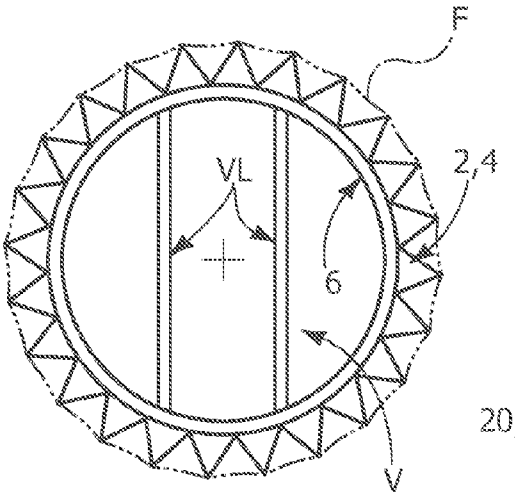


FIG. 12B

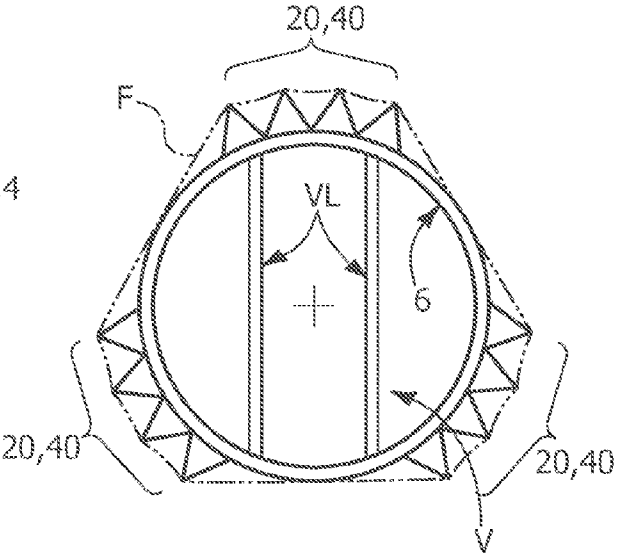


FIG. 12C

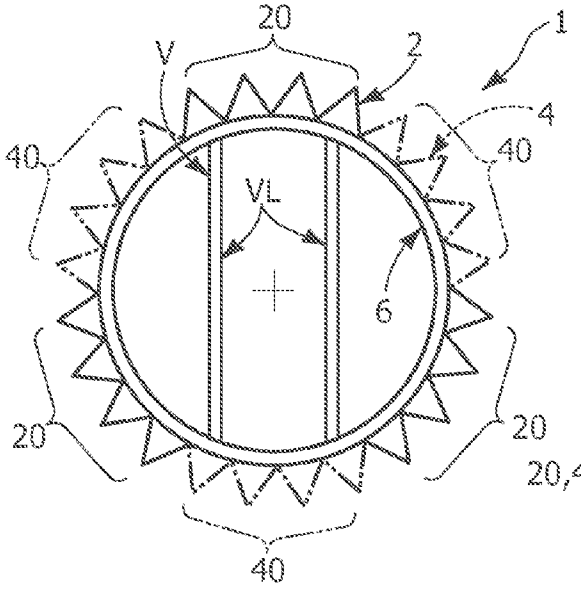


FIG. 12D

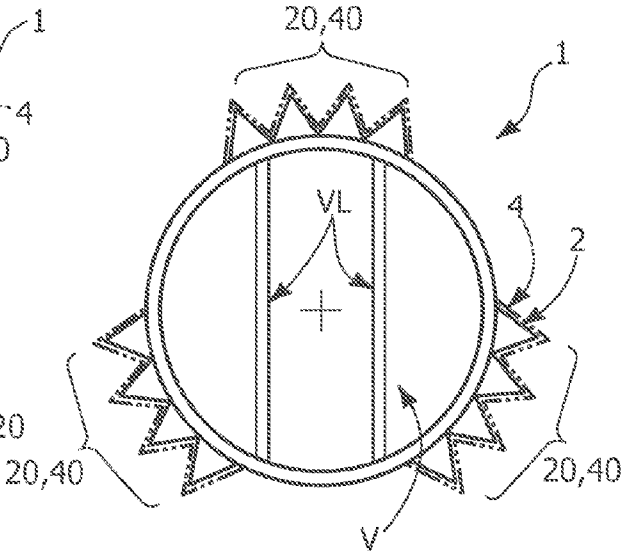


FIG. 13

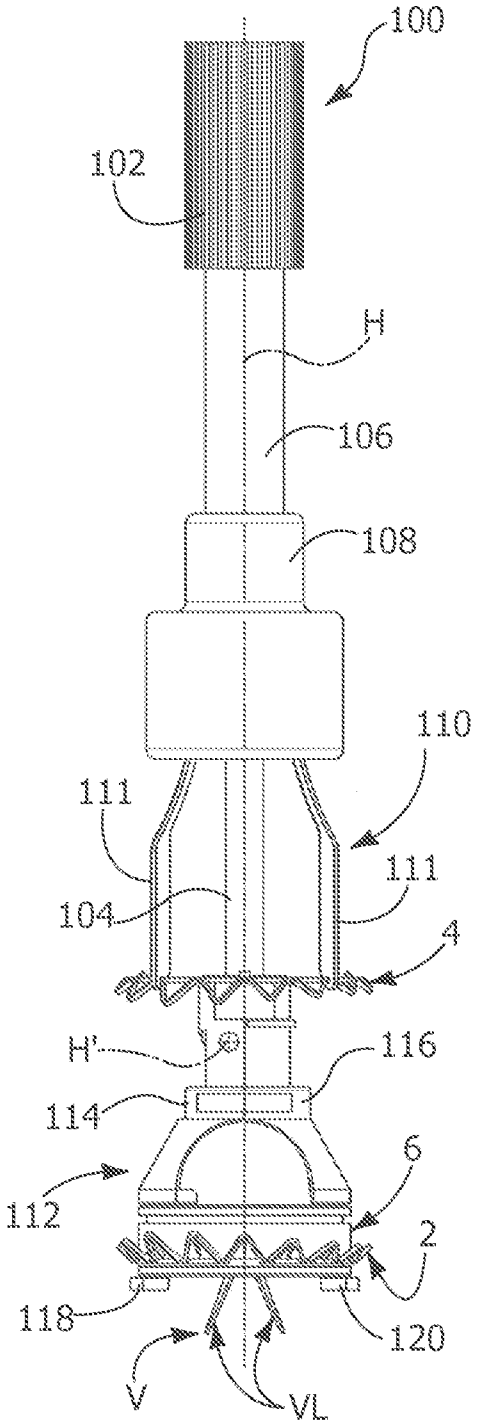

100
102
H
106
108
110
111
111
104
4
H'
116
114
6
112
2
118
120
V
VL

FIG. 14

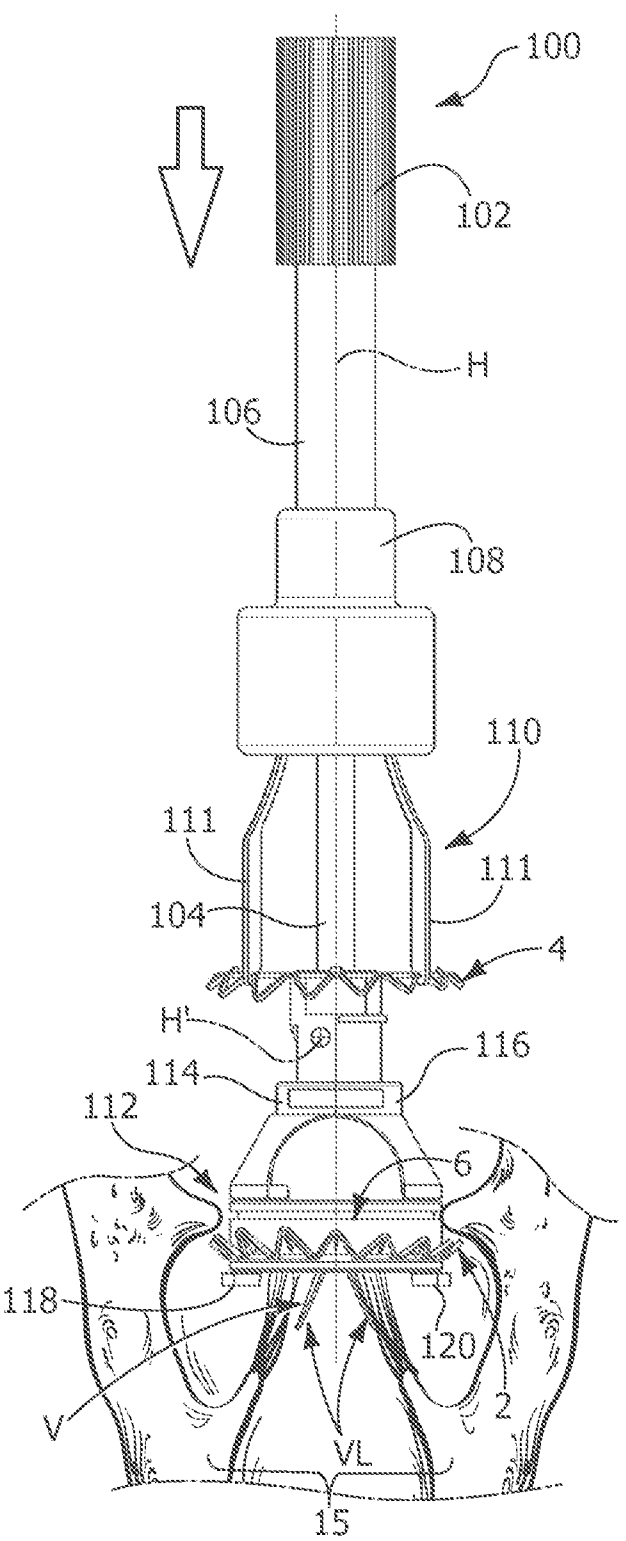
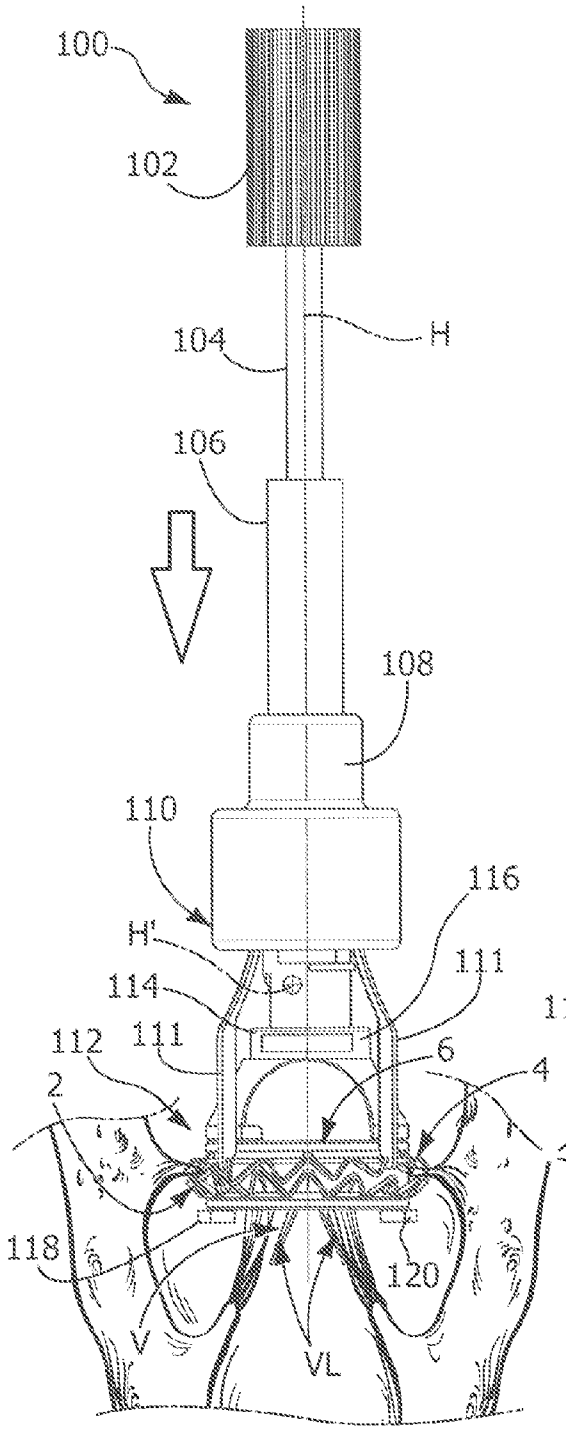

100
102
H
106
108
110
111
111
104
4
H'
116
114
112
6
118
120
2
V
VL
15

FIG. 15


100
102
104
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VL

FIG. 16

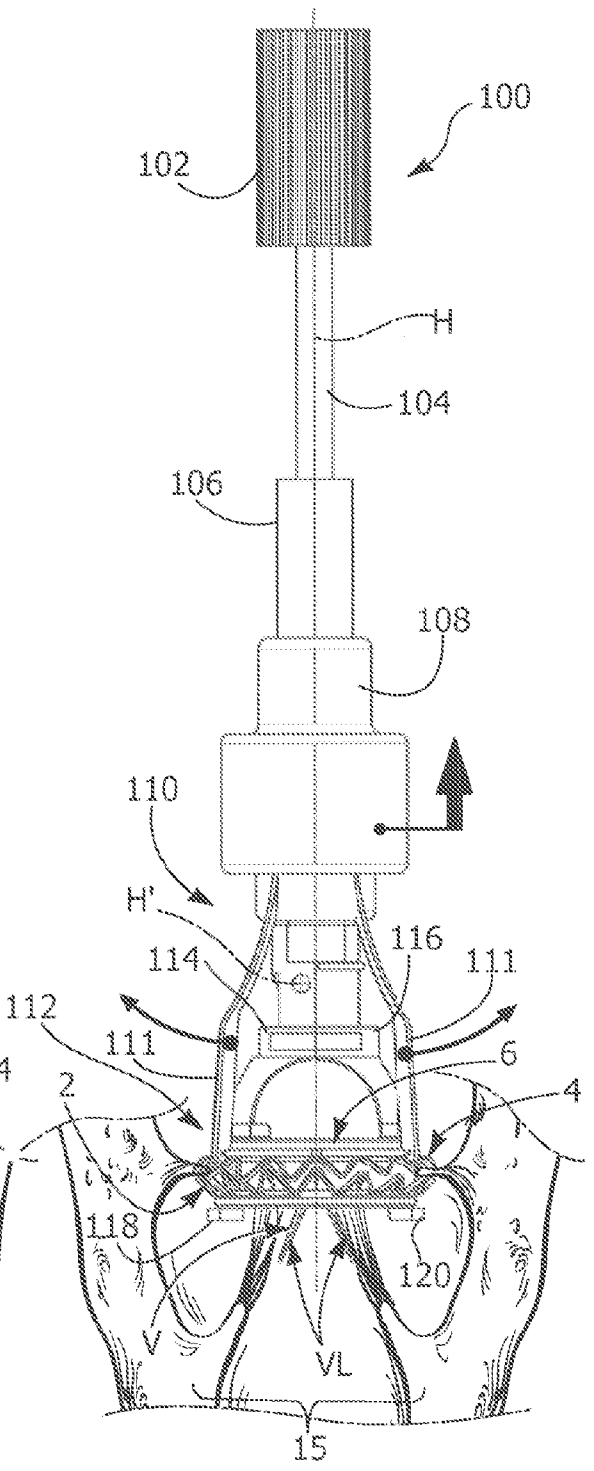
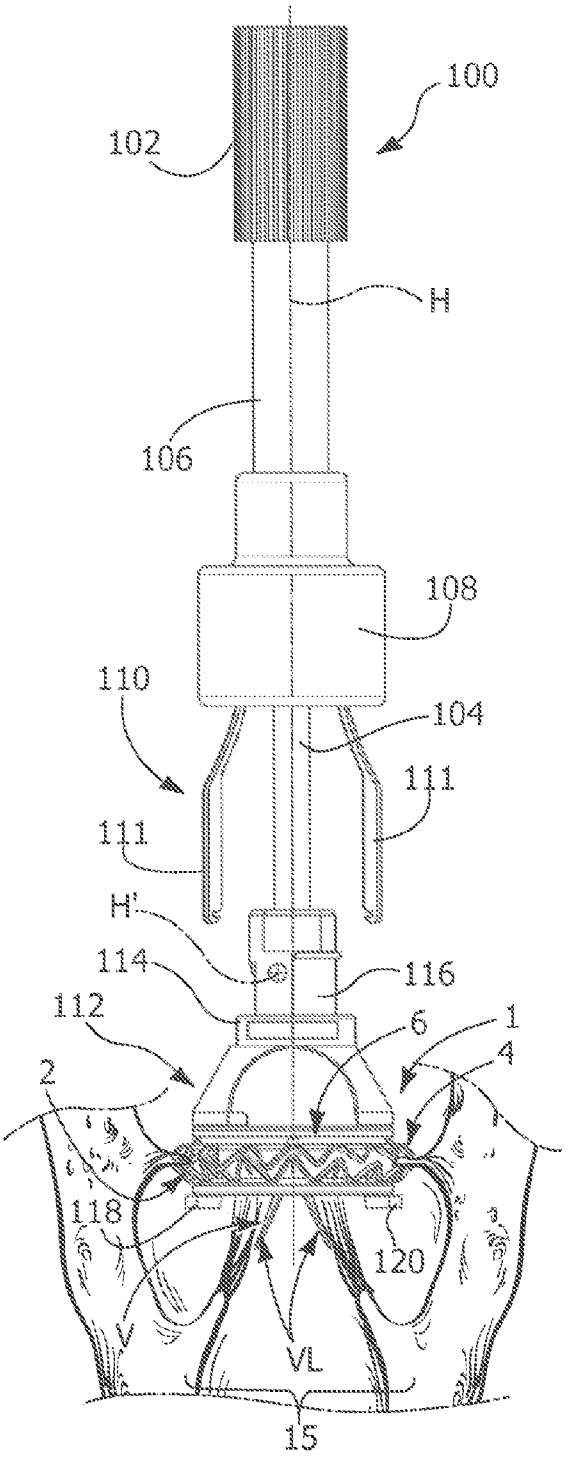

100
102
H
104
106
108
110
H'
116
111
114
112
111
6
4
2
118
120
VL
15

FIG. 17


100
102
H
106
108
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111
H'
114
116
112
6
1
4
2
118
120
V
VL
15

FIG. 18

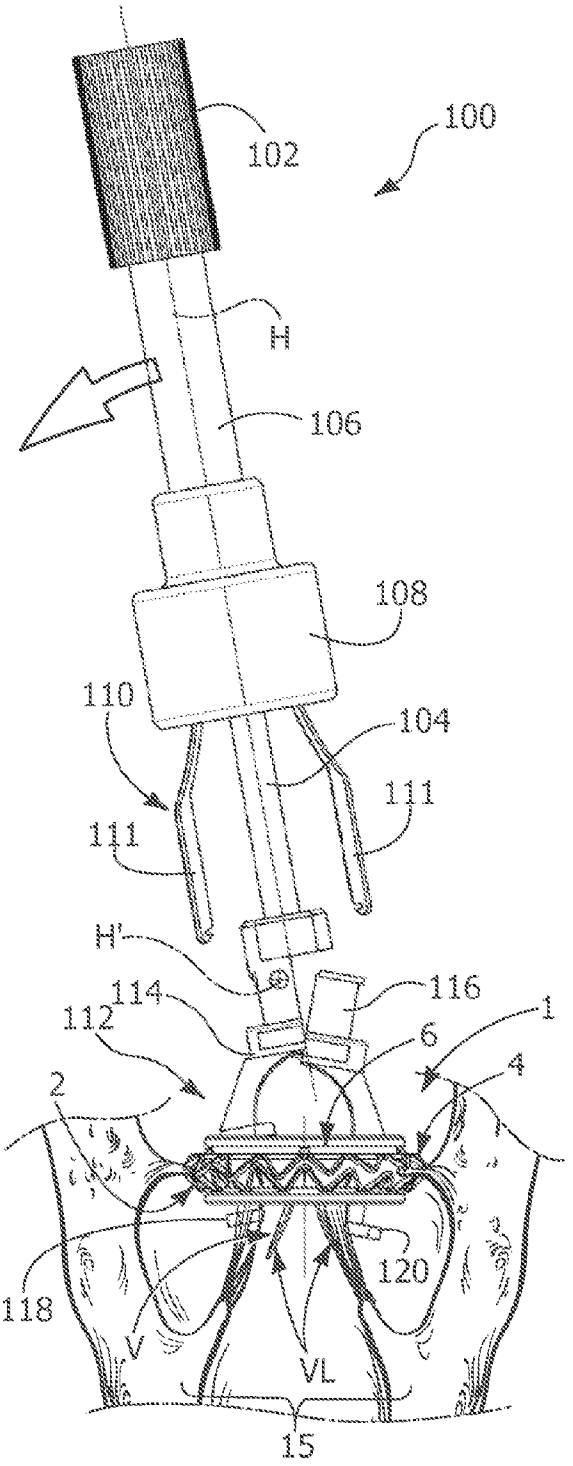
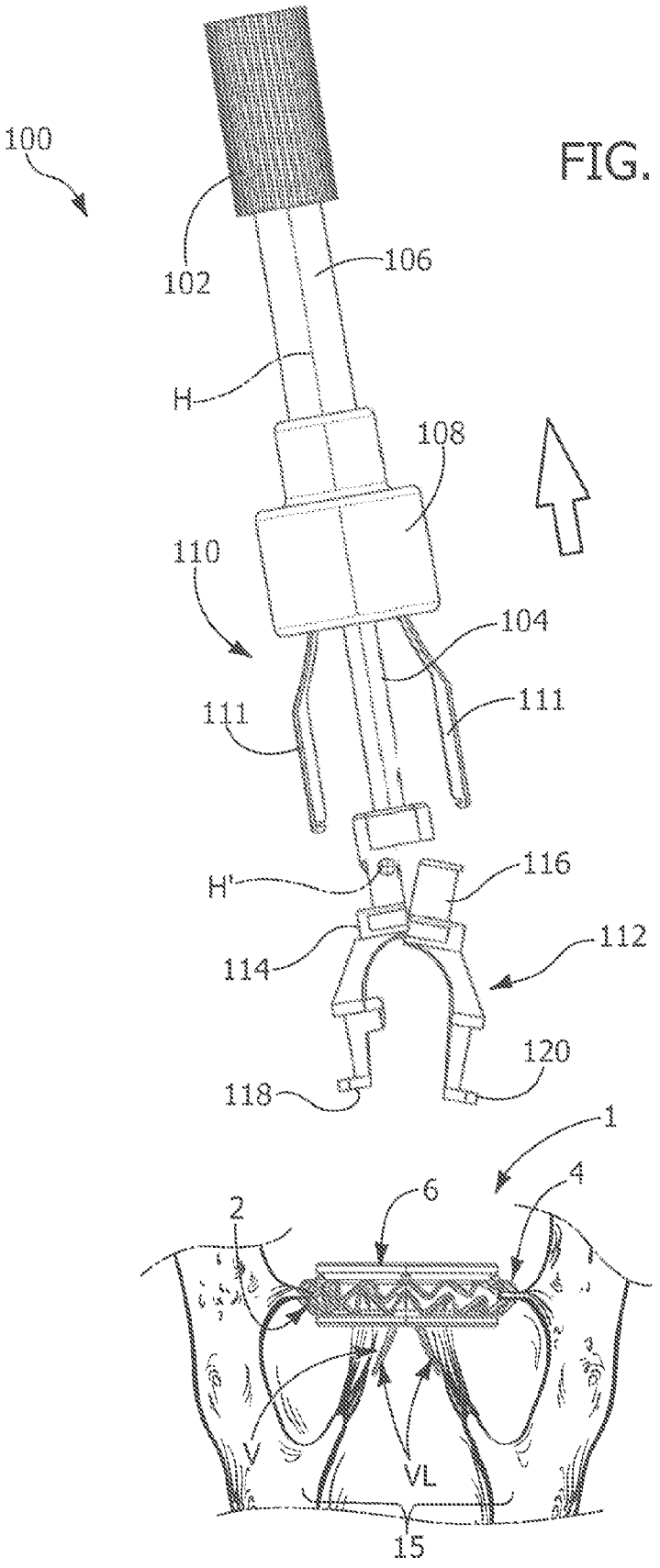

100
102
H
106
108
110
104
111
111
H'
114
116
112
6
1
4
2
118
120
V
VL
15

FIG. 19



SUTURELESS ANCHORING DEVICE FOR CARDIAC VALVE PROSTHESES

CROSS-REFERENCE TO RELATED APPLICATION

This application is a national phase application of PCT Application No. PCT/IB2012/050608, internationally filed Feb. 10, 2012, which claims priority to European Application No. 11425030.1, filed Feb. 14, 2011, both of which are herein incorporated by reference in their entirety.

TECHNICAL FIELD

The present description relates to cardiac valve prostheses adapted for sutureless anchoring, anchoring systems for use with cardiac valve prostheses, and techniques and instruments for anchoring cardiac valve prostheses to an implantation site.

Exemplary cardiac valve prostheses may be prostheses for the replacement of the mitral valve or the aortic valve of the heart.

BACKGROUND

Anchoring a prosthesis to its implantation site may play a key role in implanting cardiac valve prostheses.

Implantation performed in an easy and rapid manner may reduce the risks related to procedures that are complex and/or long to perform.

U.S. Pat. No. 3,143,742, U.S. Pat. No. 3,546,710, U.S. Pat. No. 3,574,865 and U.S. Pat. No. 6,059,827 are representative of so-called sutureless cardiac valve prostheses, which are adapted for anchoring at the implantation site by a technique that does not require suturing the valve to the implantation site.

Once implanted, the valve must resist displacement with respect to the implantation site.

Displacement of the valve may occur, for example, as a consequence of the hydraulic pressure/thrust exerted by the blood flow or due to the movements of the beating heart.

SUMMARY

An object of the invention is to avoid the technical drawbacks previously described.

According to the invention, that object is achieved by means of a device having the features set forth in the annexed claims.

The claims form an integral part of the technical disclosure provided herein in relation to the invention.

BRIEF DESCRIPTION OF THE FIGURES

The invention will now be described purely by way of non-limiting example with reference to the annexed figures.

FIGS. **1**A-C illustrate various embodiments of an anchoring device for cardiac valve prostheses.

FIGS. **2**A-**2**D illustrate various embodiments of an anchoring device for cardiac valve prostheses.

FIGS. **3**A-D illustrate various embodiments of components of an anchoring device.

FIG. **4** illustrates an embodiment of an anchoring device coupled to an implant site.

FIGS. **5**A-B illustrate embodiments of the components shown in FIG. **3**.

FIG. **6** is a partial sectional view of an embodiment of an anchoring device.

FIG. **7** illustrates embodiments of an anchoring device, with FIG. **7**A being a sectional view along line VII-VII of FIG. **7**.

FIG. **8**A illustrates an embodiment of an anchoring device, while FIG. **8**B is a plan view of an embodiment of an anchoring device with some parts removed for the sake of clarity.

FIG. **9**A is a perspective sectional view of an anchoring device according to various embodiments.

FIG. **9**B is a plan view of an embodiment according to FIG. **9**A.

FIG. **9**C is a schematic view of features of an anchoring device according to various embodiments.

FIG. **10**A is a detailed view according to arrow X of FIG. **8**B, while FIGS. **10**B-D illustrate variants of the detail of FIG. **10**A according to various embodiments.

FIGS. **11**A-C schematically show radial sections of embodiments of anchoring devices.

FIGS. **12**A-D illustrate embodiments of anchoring devices.

FIGS. **13** to **19** illustrate a sequence of implanting a cardiac valve prosthesis with an anchoring device according to various embodiments.

DETAILED DESCRIPTION

In the following description, numerous specific details are given to provide a thorough understanding of embodiments. The embodiments can be practiced without one or more of the specific details, or with other methods, components, materials, etc. In other instances, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring aspects of the embodiments.

Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the embodiment are included in at least one embodiment. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification may be not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

The headings provided herein are for convenience only and do not interpret the scope or meaning of the embodiments.

While many of the following exemplary embodiments are shown and described with reference to repair of a mitral valve, the skilled artisan will recognize that many of these embodiments may also be used to repair or replace other heart valves.

In FIG. **1**A, reference number **1** designates as a whole an anchoring device for anchoring a cardiac valve prosthesis to an implantation site, the anchoring device **1** including a first anchoring assembly **2**, a second anchoring assembly **4** and a connection structure **6**, arranged to operatively couple the first and the second anchoring assemblies **2**, **4**.

In various embodiments, the above mentioned components may be coaxial with respect to a longitudinal axis X of the device **1**. The connection structure **6** may be configured for housing a cardiac valve prosthesis V, such as a cardiac valve prosthesis of the mechanical type with one or more artificial valve elements VL (see, e.g., FIGS. **2**A, **2**B, **2**D, **8**, **12**A to **12**D, and **13** to **19**). Such prostheses are known in the art, which makes it unnecessary to provide a detailed description herein.

In various embodiments, an artificial cardiac valve prosthesis may include an annular element O defining an orifice of the prosthesis V wherein blood flow is regulated by means one or more artificial valve leaflets. According to exemplary embodiments, these valve leaflets are formed from biological tissue or from mechanical structures (e.g., two hemi-discs or semi-circular discs).

In various embodiments, the connection structure **6** may be a ring which defines an annular element (armature or stent) O of the prosthesis V, and may be thus part of the prosthesis V, with the artificial valve leaflets installed directly within the connection structure **6**.

In various embodiments, the connection structure **6** may be configured substantially as a seat for the prosthesis V, whose annular element O may be received and fixed within the connection structure **6**.

In various embodiments, the valve prosthesis V may be a biological prosthetic valve including one or more (e.g., three) leaflets made of biological tissue stitched together to reproduce the arrangement of the natural valve leaflets.

In various embodiments, the biological prosthesis may be received within the connection structure **6**.

In various embodiments, the anchoring assemblies **2**, **4** may be physically distinct with respect to the connection structure **6**.

In various embodiments, one of the two anchoring assembly may be provided integral with the connection structure **6**.

In various embodiments, as exemplified in FIG. **1**B, the first anchoring assembly **2** may be provided integral with the connection structure **6**, while the second anchoring assembly **4** may be provided as a separate element.

In various embodiments, as exemplified in FIG. **1**C, the second anchoring assembly **4** may be provided integral with the connection structure **6**, while the first anchoring assembly **2** may be provided as a separate element.

In various embodiments, while physically distinct from the connection structure **6**, one of the two anchoring assemblies **2**, **4**, may be provided pre-installed thereon, the resulting arrangement thus being similar to embodiments wherein one anchoring assembly may be integral with the connection structure **6**.

The schematic illustration of the anchoring assemblies **2**, **4** of FIGS. **1**A-C shows that in various embodiments these assemblies may include respective anchoring formations defining an annular, possibly non-continuous structure.

In various embodiments, the anchoring assemblies **2**, **4** may be configured as a closed, continuous structure.

In various embodiments, either or both of the anchoring assemblies **2**, **4** may be discontinuous, e.g., provided as a pair of tapered hemi-rings **8**, **10** and **12**, **14** respectively.

In various embodiments, as exemplified in FIG. **2**A, the anchoring assemblies **2**, **4** may be each provided as a closed tapered ring (such a structure that can be at least roughly assimilated to a Belleville spring), the two anchoring assemblies being arranged with their respective flared portions facing each other.

In various embodiments, as exemplified in FIG. **2**C, either or both of the anchoring assemblies **2**, **4** may have a tapered shape similar to that shown in FIG. **2**A, and develop along a non-planar closed path.

In various embodiments, the anchoring assemblies **2**, **4** may be provided as tapered rings with a plurality of radial anchoring formations **16**.

In various embodiments, the anchoring formations are arranged in one or more pairs of complementary portions **20**, **40**, associated with the anchoring assemblies **2**, **4**, respectively. According to various embodiments, the complementary portions **20**, **40** are arched portions associated with corresponding or complementary portions of the circumference of the anchoring assemblies.

In various embodiments, the anchoring formations **16** are configured as integral extensions of the corresponding anchoring assemblies.

In various embodiments, as exemplified in FIGS. **3**A to **3**D, the anchoring assemblies **2**, **4** may have a variety of different structures.

In various embodiments, as exemplified in FIG. **3**A, either or both of the anchoring assemblies **2**, **4** may be configured as an open annular element. Such a structure will exhibit a certain degree of circumferential deformability.

In various embodiments, either or both of the anchoring assemblies **2**, **4** may be configured as closed annular elements including at least one recess shaped portion **18** that provides a certain deformability, i.e., either or both the anchoring assemblies **2**, **4** may be configured as expandable closed rings.

In various embodiments, regardless their structure (i.e., open or closed), either or both of the anchoring assemblies **2**, **4** may be provided with one or more inner radial teeth **19**.

In various embodiments, the anchoring formations of each arched portion may be bent towards the complementary arched portion.

In various embodiments, these anchoring formations are substantially saw-tooth shaped.

In various embodiments, as exemplified in FIG. **4**, the anchoring device **1** may be configured to provide a firm anchoring of a cardiac valve prosthesis to an implantation site without suture being required.

Such anchoring may be achieved in various embodiments by securing (e.g., capturing, sandwiching or pinching) portions of native biological tissue of the implantation site between the anchoring assemblies **2**, **4**. The native biological tissue may be pinched between the anchoring assemblies **2**, **4** as they are coupled together for example by means of the connection structure **6**.

In various embodiments, the implantation site may be the mitral valve annulus.

In various embodiments, as exemplified in FIG. **5**A, either or both the anchoring assemblies **2**, **4** may include a base body such as an open annular element **22** (similar to those of the embodiments of FIGS. **3**A, **3**C) having, extending radially outwardly therefrom, a crown of anchoring formations **24** having a saw-tooth profile similar to that of the anchoring formations **16** but each provided with an aperture **26**, e.g., triangular in shape.

In various embodiments, at least some of the anchoring formations **24** may not have such apertures, thereby having a solid configuration more similar to that of the anchoring formations **16**.

In various embodiments, the anchoring formations **24** are configured as integral extensions of the corresponding anchoring assemblies.

In various embodiments, teeth **19** may be provided in the base body **22**, e.g. internally thereof.

In various embodiments, the anchoring formations **24** may have different radial extensions along the ring **8**.

In various embodiments, as exemplified in FIG. **5**B, either of both of the anchoring assemblies **2**, **4** may include a base body such as a closed annular element **28** (similar to those of the embodiments of FIGS. **3**B, **3**D) and a plurality of anchoring formations **24**, possibly provided with openings **26**, arranged in groups alternate to the recess-shaped portions **18**.

In various embodiments, the anchoring formations **24** (whether provided with the triangular openings **26** or not)

may be arranged to confer a substantially tapered shape to the anchoring assemblies **2**, **4**. That is, the anchoring formations **24** (as well as, in various embodiments, the recess-shaped portions **18**) may be arranged so as to lie substantially at an angle with respect to the plane of the respective base body **22**, **28**.

In various embodiments, in correspondence with at least one pair of complementary arched portions having anchoring formations for anchoring on said native biological tissue located at or near the valve annulus, the anchoring formations include integral extensions of the anchoring assemblies **2**, **4** extending radially outwardly of one of the anchoring assemblies in an alternate arrangement with respect to corresponding extensions extending radially outwardly of the other anchoring assembly. In various embodiments, these corresponding extensions may be similar or generally homologous to each other. Each anchoring formation of one anchoring assembly **2**, **4** may thus be located, when the anchoring assemblies are coupled by the connection structure **6**, between two adjacent formations of the other anchoring assembly, whereby the anchoring formations of the two anchoring assemblies, once coupled, give rise to an interdigitated (i.e., intertwined or intermingled) arrangement. That is, with the anchoring assemblies **2**, **4** mutually coupled to secure the biological tissue, the extensions in the two complementary arched portions interdigitate and impart to the biological tissue secured therebetween a serpentine trajectory.

This may improve the stability of the anchoring device at the implantation site because the biological tissue at the implantation site may become trapped and pinched between the anchoring assemblies **2**, **4** thus being tensioned, stretched and firmly held.

In various embodiments, the anchoring formations **24** (irrespective of whether solid or apertured) may be elastically deformable.

In various embodiments, the connection structure **6** may be a ring element including one or more coupling profiles adapted to receive the anchoring assemblies **2**, **4**.

In various embodiments, as exemplified in FIG. **6**, such coupling profiles may include annular grooves G, e.g., with a groove G for each anchoring assembly **2**, **4**.

In various embodiments, wherein the anchoring assemblies include radial teeth **19**, only one assembly **2**, **4** may be configured to engage within the groove G. In various embodiments, without the teeth **19**, an annular portion of the base body may engage the groove G.

In various embodiments, at least one anchoring assembly may be configured as a closed annular element (e.g., as exemplified in FIGS. **2**A, **2**C, **2**D, **3**B, **3**D, **5**B) and that anchoring assembly may be coupled with the connection structure **6** (e.g., by snap-engagement) within a corresponding groove G by means of an elastic and, possibly, an additional plastic deformation of the anchoring assembly (which may be facilitated by the recess shaped portions **18**, where present).

In various embodiments, at least one anchoring assembly may be configured as an open annular element (e.g., as exemplified in FIGS. **3**A, **3**C, **5**A). Such an anchoring assembly may be coupled with the connection structure **6** by radially expanding it by moving apart the free ends thereof, by engaging the inner rim of the radially expanded anchoring assembly within a corresponding annular groove G and then letting the anchoring assembly contract again elastically so that the inner rim thereof is captured in the annular groove G.

In various embodiments, the anchoring formations may extend over different radial lengths around the outline of the corresponding base body.

In various embodiments, as exemplified in FIG. **7**, either or both the anchoring assemblies **2**, **4** may include a base body such as an annular element **30** (either open or closed), having a plurality of anchoring formations **32** extending radially outwardly therefrom.

In various embodiments, the anchoring formations **32** may be configured as integral extensions of the corresponding anchoring assemblies.

In various embodiments, the formations **32** may be substantially saw-tooth shaped and/or provided with (e.g., triangular) apertures **34**.

In various embodiments, at least part of the anchoring formations **32** may not have a corresponding triangular aperture **34**. In various embodiments, the anchoring assemblies **2**, **4** may be provided with the teeth **19**.

In various embodiments, the anchoring formations **34** may form an angle with respect to the plane base body so as to confer an overall tapered shape to the anchoring assembly to which they belong.

In various embodiments, the anchoring formations **32** (irrespective of whether solid or apertured) may be elastically deformable.

In various embodiments, each of the anchoring assemblies **2**, **4** may be symmetrical with respect to a transverse axis X**1** ("transverse" being in a direction substantially lying in the plane of the closed annular element **30** and orthogonal to the longitudinal axis X) and the anchoring formations **34** may have their radial extension increasing over a first angle α_1 and then decreasing over a second angle α_2, wherein the sum of the angles $\alpha_1+\alpha_2$ may be equal to 180°. This may confer to the corresponding anchoring assembly **2**, **4** (or both) a substantially D-shaped outline (in plan view), which renders the anchoring device **1** more easily adaptable to implantation sites such as, for example, the mitral valve annulus.

In various embodiments, the sum of the angles $\alpha_1+\alpha_2$ may be equal to 120°, so that three groups of anchoring formations, each extending over 120°, may be provided on the anchoring assemblies and confer thereto a substantially three-lobed outline (in plan view), which renders the anchoring device **1** more easily adaptable to implantation sites such as, for example, the pulmonary valve annulus or the tricuspid valve annulus.

In various embodiments, adjacent anchoring formations **32** may be angularly spaced from each other thereby defining a crown of angular gaps.

In various embodiments as exemplified in FIGS. **7** and **7**A, these angular gaps may provide a sort of interpenetration (i.e., intertwining) of the anchoring assemblies **2**, **4**. In other words, with reference to FIG. **7**, at least one pair of complementary arched portions of the anchoring assemblies are configured according to the embodiments exemplified in FIG. **6**, each anchoring formation **32** of one anchoring assembly will extend between two subsequent (and spaced apart) anchoring formations of the other anchoring assembly. The anchoring formation will thus interdigitate and impart to the native biological tissue secured (e.g., pinched) therebetween a substantially serpentine-like trajectory. Such serpentine-like trajectory may include, for example, subsequent sinusoidal-like portions having a length in the range between 2 mm and 15 mm. The term "length" associated to the sinusoidal-like trajectory is used herein to indicate the "wavelength" of such sinusoidal-like trajectory, namely the distance between the free ends (e.g., the vertices) of two subsequent anchoring formations of an anchoring assembly (which is in the range between 2 and 15 mm as well), which substantially corresponds to subsequent peaks/valleys of the biological tissue.

With reference to FIGS. **9**A, **9**B, **9**C, in various embodiments, the anchoring assemblies **2**, **4** may be arranged so that at least one, preferably more than one, pair of anchoring formations **32** interdigitate and at least one, preferably more than one, pair of anchoring formations **32** form couples of co-operating extensions, i.e., they are substantially angularly aligned and do not interdigitate.

In various embodiments, the anchoring assemblies **2**, **4** are configured so as to have a substantially D-shaped plan outline (as, for example, those exemplified in FIGS. **7**, **8**A, **8**B, **9**A, **9**C) which allows a better adaptation to the mitral valve annulus. Also, the anchoring assemblies **2**, **4** may be configured so that a group of anchoring formations **32** provided along a curved portion of such D-shaped outline (associated to a posterior cusp PC of the mitral valve) of each of the anchoring assemblies **2**, **4** are arranged so as to be angularly aligned (i.e., they do not interdigitate) while another group of anchoring formations **32** provided along a straight portion of such D-shaped outline (associated to an anterior cusp AC of the mitral valve) of each anchoring assembly **2**, **4** interdigitate.

This arrangement is exemplified in the embodiments shown in FIGS. **9**A, **9**B, wherein FIG. **9**A shows a sectional view of the human heart and particularly of an implant site (that is, the mitral valve annulus). The view of the annulus is taken partly along a substantially curved trajectory so as to show the portions of biological tissue pinched between the anchoring assemblies **2**, **4**. The biological tissue pinched in the area of the anterior cusp AC has, therefore, a serpentine like trajectory, (FIGS. **9**A, **9**C), while the biological tissue pinched in the area of the posterior cusp PC has a substantially linear trajectory. With reference to FIG. **9**C, in the area of the posterior cusp PC, the contact between the anchoring formations may be mainly localized in corresponding of contact areas A, while in the area of the anterior cusp AC the contact may be mainly distributed over the interdigitating anchoring formations **32**. FIG. **9**C shows a schematic representation of such condition.

According to various embodiments, in the area of the anterior cusp AC, the biological tissue, due to the annulus characteristics and surgical preparation of the implant site, offers a larger gripping area than that in the area of the posterior cusp PC. The anchoring assemblies/formations may be more rigid in correspondence with the anterior cusp (where the formations interdigitate), while they may be more elastic in correspondence of the posterior cusp PC (where the formations do not interdigitate and are deformed to compensate the different stiffness or thickness of the tissue in the area of the posterior cusp PC).

In various embodiments, the anchoring device **1** may include anchoring assemblies **2**, **4** having different degrees of stiffness (i.e., one assembly stiffer than the other).

Various embodiments may adopt a degree of stiffness varying along (i.e., over the annular extension of) each anchoring assembly.

In various embodiments, as exemplified in FIG. **6** (or FIG. **9**) anchoring formations having differentiated flexural stiffness (i.e., with respect to bending with respect to the plane of the base body) may be provided, that is, with adjacent or subsequent anchoring formations have different flexural stiffness. In various embodiments, however, the stiffness variation may be "step-wise", that is with the degree of stiffness variable over the anchoring assembly while being constant along certain portions thereof.

A differentiated degree of stiffness allows the anchoring assemblies to better adapt to the implantation site, e.g., to allow for the thickness of the biological tissue trapped between the anchoring assemblies **2**, **4** being uneven due to the anatomy of the implantation site and/or the method used to trap the tissue. Such unevenness may be counterbalanced by a differentiated flexural stiffness of the anchoring formations, which can be rendered more flexible, e.g., in those areas where the biological tissue may be expected to be thicker.

In various embodiments, the flexural stiffness of the anchoring formations **24**, **32** may be varied according to the anatomy of the implantation site: for example, as previously exemplified, the flexural stiffness of the anchoring formations may be differentiated on the basis of their locations with respect to the implantation site, that is depending on whether the anchoring formations are located at the anterior cusp or at the posterior cusp of the native mitral valve.

In various embodiments, as exemplified in FIGS. **8**B and **10**A-D, the anchoring formations **32** may be provided with tines or barbs **36**.

In various embodiments, the tines or barbs **36** may protrude radially inwardly of the corresponding anchoring assembly and/or may be located substantially in correspondence of a vertex C of the corresponding anchoring formations **32**.

In various embodiments, the tines or barbs **36** may protrude radially inwardly of the corresponding anchoring assembly in a plane different from the plane of the corresponding anchoring formation **32**. In various embodiments, the tines or barbs **36** may protrude radially inwardly of the corresponding anchoring assembly in a substantially co-planar configuration with respect to the plane of the corresponding anchoring formation **32**.

In various embodiments, as exemplified in FIG. **9**, each anchoring formation **32** may be provided with a sting **36**. In various embodiments, only some of the anchoring formations **32** may be provided with tines or barbs **36**.

In various embodiments, as exemplified in FIGS. **10**B-D, the arrangement of the tines or barbs **36** may be vary and/or the tines or barbs may be replaced with similar members.

In various embodiments, as exemplified in FIG. **10**B, at least some of the anchoring formations **32** may be provided with more than one tine or barb **36**, for example three tines or barbs arranged as the vertices of a triangle.

Irrespective of whether arranged in groups or singly on the anchoring formations **36**, the tines or barbs may be configured to penetrate the biological tissue trapped between the anchoring assemblies **2**, **4** thereby enhancing the stability of the anchoring device **1** at the implantation site.

In various embodiments, as exemplified in FIG. **10**C, a plurality of saw-like teeth **38** may be provided around the outline of the anchoring formations **32** (i.e., along the struts surrounding the triangular aperture **34**).

In various embodiments, as exemplified in FIG. **10**D, a hook **39** may be provided at vertex C of at least some of the anchoring formations **32**.

Both the teeth **38** and the hooks **39** may be configured to penetrate into the biological tissue at the implantation in order to improve the stability of the anchoring device at the implantation site.

In various embodiments, the arrangements and/or elements described above may be freely combined to meet specific needs, e.g., in the case of an implantation site requiring anchoring assemblies having different features at different locations.

In various embodiments, as exemplified in FIGS. **11**A-C, coupling of the anchoring assemblies to the connection structure **6** may be provided in different ways.

In various embodiments, as exemplified in FIG. **11**A, the anchoring assembly **2** may be provided integral with the connection structure **6** while the anchoring assembly **4** may be provided as a separate element configured for the engage-

ment within an annular groove G provided in the connection structure **6**. In various embodiments, such a mutual arrangement may be reversed, that is with the anchoring assembly **4** integral with the connection structure **6** and the anchoring assembly **2** being a separate element.

In various embodiments, as exemplified in FIG. **11**B, the anchoring assembly **2** may be provided integral with the connection structure **6** while the anchoring assembly **4** may be provided as a separate element configured to fit axially on the connection structure **6**, supported by an abutment surface **41**. The anchoring assembly **4** may then be fixedly attached to the connection structure **6** by means of a ring **42** (e.g., a ring nut or a deformable ring). Again, the mutual arrangement described may be reversed according to the needs.

In various embodiments, as exemplified in FIG. **11**C, the anchoring assembly **2** may include a plurality of fingers **42** having a head **44** substantially shaped in a harpoon-like fashion. Each finger **42** may be configured to snap-engage a slot **46**, which after the engagement defines an abutment surface for the head **44** which maintains the anchoring assemblies **2**, **4** connected to one another. In that case, the connection structure **6** may be provided by a circular array of fingers **42** protruding axially from the anchoring assembly **2**.

In various embodiments, such an arrangement may be reversed by providing the fingers **42** on the assembly **4**, while in various embodiments the fingers **42** may be provided partly on the assembly **2**, and partly on the assembly **4**. The prosthesis V may then be housed within a circular "cage" as created by the fingers **42**.

In various embodiments, as exemplified in FIGS. **12**A-**12**B, the anchoring assemblies **2**, **4** may be provided as an annular continuum of radially protruding anchoring formations (FIG. **12**A), while in other embodiments they may be arranged in separate sectors (defining the anchoring elements **20**, **40**) of adjacent anchoring formations, as shown in FIG. **12**B. In other words, in various embodiments such as those exemplified in FIG. **12**A, the device **1** may include a one-by-one alternate arrangement of individual anchoring formations carried by one and the other of the complementary arched portions of the anchoring assemblies **2**, **4**, respectively. In other embodiments, such as those exemplified in FIG. **12**B, instead, the device **1** may include an alternate arrangement of groups of anchoring formations, such alternated groups being carried by one and the other of the complementary arched portions of the anchoring assemblies **2**, **4**, respectively.

In various embodiments, the anchoring assemblies **2**, **4** may include a sealing member forming an impermeable surface coupled to at least one of the anchoring assemblies. In various embodiments, the sealing member may extend to cover the anchoring formations (e.g., the anchoring formations **16**, **18**, **24**, **32**) of the corresponding anchoring assembly **2**, **4**.

In various embodiments, such sealing member may be a sheath, preferable a textile sheath, F (illustrated in phantom line) vested onto at least one of the anchoring assemblies. Such sheath F may provide a sealing action (e.g., against blood leaks) between the anchoring device **1** and the implantation and may be configured to promote tissue covering (regrowth).

In various embodiments, the anchoring assemblies **2**, **4** may exhibit a discontinuous structure (as exemplified in FIG. **12**B) and the anchoring device **1** may be provided with a continuous fabric enclosure F to prevent blood leaks.

In various embodiments, as exemplified in FIGS. **12**C and **12**D, sectors **20**, **40** of the anchoring assemblies **2**, **4** may be arranged in an alternated fashion (FIG. **12**C) or substantially overlapped (FIG. **12**D).

In various embodiments, a combination of such arrangements may be provided, with the sectors **20**, **40** at least partly overlapping.

FIGS. **13** to **19** illustrate, purely by way of non-limiting example, a method for anchoring a cardiac valve prosthesis with a device according to one or more of the embodiments.

While implantation as described herein refers by way of example to the mitral valve, it will be appreciated that the description applies independently of the implantation site. For example, the skilled artisan will recognize that the methods may apply to implanting a prosthetic valve, e.g., at the pulmonary valve annulus or the tricuspid valve annulus. Also, while implantation as described herein refers to an antegrade approach, this is not to be construed as limitative of the scope of the invention.

With reference to FIG. **13**, reference number **100** designates an instrument for positioning and securing to an implantation site an anchoring device according to one or more of the embodiments.

The instrument **100** extends along a longitudinal axis H and may include a handle **102** fitted on a shaft **104** having a tubular element **106** slidably mounted thereon. A sleeve **108** may in turn be slidably mounted on the tubular element **106**.

In various embodiments, as exemplified herein, the tubular element **106** carries a first gripping assembly including, e.g., four fingers **111**. The fingers **111** may be hinged to the tubular element **106** by "living" hinges L (see FIG. **16**) which bias the fingers **111** away from the axis H. In addition to protruding axially, the fingers **111** may also protrude radially.

The sleeve **108** may be configured to slide over the living hinges L and maintain the fingers **111** as close as possible to the axis H.

A second gripping assembly **112** may be in turn be carried by the shaft **104**. The gripping assembly **112** has a substantially fork-like arrangement including first and second gripping members **114**, **116** each having a respective locking foot **118**, **120**.

For reasons detailed below, one of the two locking members **114**, **116** may be displaceable with respect the position illustrated in FIG. **10**.

With reference again to the example of FIG. **11**, the anchoring device **1** may be installed on the instrument **100** in a partially disassembled configuration.

In any of the embodiments previously described, the second anchoring assembly **4** may be retained on the fingers **111** while the first anchoring assembly **2** may be installed on the connection structure **6**, which houses the cardiac valve prosthesis. The gripping members **114**, **116** may be engaged within the connection structure **6**, which may be prevented from disengagement by means of the locking feet **118**, **120**.

At the time the anchoring device **1** and the cardiac valve prosthesis V are mounted on the instrument **100**, the tubular element **106**, the distal sleeve **108** and the first gripping assembly **110** may be maintained in a proximal position, substantially adjacent to the handle **102**, so that the second anchoring assembly may be axially separated with respect to the reminder of the anchoring device **1** (FIG. **13**).

It will be appreciated that, as used herein, "proximal" and "distal" refer to the structure of the instrument, with the handle **102** taken as the proximal reference.

The instrument **100** (FIG. **14**) may then be advanced to the implantation site to bring the elements of the anchoring device **1** carried by the second gripping assembly **112** on that part of the implantation site opposite to the elements carried by the first gripping assembly **110**. The two separate portions

of the anchoring device **1** carried by the instrument **100** will thus lie astride of the implantation site (e.g., the mitral valve annulus).

With the second gripping assembly **112** positioned to cause the two portions of the anchoring device **1** to be positioned astride of the valve annulus and the first anchoring assembly **2** in contact with the walls of the implantation site, one or more portion of biological tissue at the implantation site may be trapped by the anchoring assembly **2**, for example, by the anchoring formations **24**, **32**.

If the tines or barbs **36**, or any of the teeth **38** and the hooks **39**, are provided on the anchoring formations, the biological tissue may be fixed on the anchoring formation **2** by penetrating the tissue with the tines or barbs **36** (or the teeth **38**/hooks **39**).

The tubular element **106** may be then be advanced along the shaft **104** (i.e., toward the distal end of the instrument) in order to couple the second anchoring assembly **4** on the connection structure **6**.

The tissue at the implantation side which was previously trapped on the first anchoring assembly **2** will now be firmly secured (e.g., pinched) by and between the anchoring assemblies **2**, **4** coupled by means of the connection structure **6** (FIG. **15**).

As exemplified in FIG. **16**, the sleeve **18** may be then retracted in a proximal direction in order to release the fingers **111** and let them spread apart due to the outward bias of the living hinges L. This will result in the fingers **111** being disengaged from the anchoring assembly **4**.

As exemplified in FIG. **17**, the tubular element **106** may be retracted in a proximal direction away from the implant site.

In various embodiments, the anchoring assembly **4** may be provided with an open ring structure, and the implantation procedure may be aborted by dilating the anchoring assembly **4** with a dilator tool in a way at least roughly similar to dilating so-called "Seeger" elastic rings in mechanics. The anchoring assembly **4** may be disengaged even if provided as a closed annular element by simply deforming and removing it.

As exemplified in FIG. **18**, disengagement of the second gripping assembly **112** from the device **1** and from the cardiac valve prosthesis V may be effected by displacing the gripping element **116** with respect to the gripping member **114**. This may be achieved by rotation (here clockwise, see R) around an axis H', transversal the longitudinal axis H, which substantially results in a displacement of the foot **120** inwardly of the connection structure **6**, so that the retaining action exerted thereon is released.

The instrument **100** may then be removed by simply withdrawing it from the implantation site as the instrument **100** is no longer coupled to the anchoring device **1**.

The cardiac valve prosthesis V may be then fixed to the anchoring device **1**, which is in turn firmly anchored to the implantation site due to the pinching action exerted by the anchoring assemblies **2**, **4** on the native biological tissue sandwiched (pinched) therebetween.

Accordingly, the anchoring device **1** enables, sutureless implantation of the cardiac valve prosthesis V, which reduces the time required for the intervention (and the complexity thereof as well), to the advantage of the safety for the patient. No time-consuming suturing operations are required by the practitioner, since anchoring at the implantation site is achieved just by manipulating portions of biological tissue at the implantation site in order to trap the tissue between the anchoring formations **2**, **4**.

In various embodiments, the anchoring assemblies **2**, **4** may be a metallic material including chrome-cobalt alloys (Cr—Co alloys), stainless steel, superelastic metal alloys or polymeric materials.

In various embodiments, the stress-strain curve of the material of the anchoring assemblies **2**, **4** may be chosen to allow a correct entrapment of the portions of tissue even if the amount or thickness of the biological tissue being trapped may be uneven over the perimeter of the anchoring device. This may be achieved, for example, by using superelastic alloys (e.g., Nitinol).

In various embodiments, the anchoring assemblies **2**, **4** may be of an expandable type (e.g., superelastic materials), thus permitting implantation of the device **1** together with the cardiac valve prosthesis V even percutaneously through the vascular system or via small incisions in the skin. In various embodiments, the anchoring assemblies **2**, **4** may have a coating which may be biocompatible and hemocompatible.

Naturally, without departing from the principles of the invention, the details and the embodiments may vary, even significantly, with respect to what has been described and illustrated, without departing from the scope of the invention as defined by the annexed claims.

The invention claimed is:

1. A device for anchoring a prosthetic heart valve on biological tissue, the device comprising: first and second anchoring assemblies that are mutually couplable to secure biological tissue therebetween, wherein the anchoring assemblies include at least one pair of complementary arched portions having anchoring formations for anchoring on the biological tissue, such that the anchoring formations include extensions which are rigidly connected to the anchoring assemblies and extend radially outwardly from one of the anchoring assemblies in an aligned arrangement with respect to corresponding extensions extending radially outwardly from the other of the anchoring assemblies, whereby, with the anchoring assemblies mutually coupled to secure the biological tissue therebetween, the extensions in the pair of complementary arched portions form couples of co-operating extensions, wherein, in at least one of the anchoring assemblies, the extensions have different lengths over different portions of the respective anchoring assemblies.

2. The device of claim **1**, wherein the extensions are elastically deformable.

3. The device of claim **1**, wherein, in at least one of the arched portions, the extensions are bent toward the complementary arched portion.

4. The device of claim **1**, wherein, in at least one of the arched portions, the extensions are elastically biased towards the complementary arched portion.

5. The device of claim **1**, wherein the extensions taper, preferably sawtooth-like, radially outwardly of the arched portions.

6. The device of claim **1**, wherein at least part of the extensions have an apertured structure.

7. The device of claim **1**, wherein at least one of the anchoring assemblies includes an annular base body having the anchoring formations as integral extensions thereof.

8. The device of claim **7**, wherein the complementary arched portions extend over the whole of the anchoring assemblies, whereby the anchoring formations form a crown of integral extensions surrounding the annular base body.

9. The device of claim **7**, wherein the complementary arched portions extend over respective portions of the anchoring assemblies, whereby the anchoring formations include at least one angular sector of integral extensions of the annular base body.

10. A device for anchoring a prosthetic heart valve on biological tissue, the device comprising: First and second anchoring assemblies that are mutually couplable to secure biological tissue therebetween, wherein the anchoring assemblies include: at least one first pair of complementary arched portions having extensions in an aligned arrangement to form couples of co-operating extensions securing therebetween the biological tissue in a linear trajectory; and at least one second pair of complementary arched portions having integral extensions extending radially outwardly of one of the anchoring assemblies in an alternate arrangement with respect to homologous extensions extending radially outwardly of the other of the anchoring assemblies, whereby, with the anchoring assemblies mutually coupled to secure the biological tissue the extensions in the second pair of complementary arched portions interdigitate and impart to the biological tissue secure therebetween a serpentine-like trajectory.

11. The device of claim 10, wherein the anchoring assemblies have a substantially D-shaped plan outline.

12. The device of claim 10, wherein the anchoring assemblies have a substantially D-shaped plan outline, at least one of the first pair of complementary arched portions is arranged at the curved portion of the D-shaped outline, and at least one the second pair of complementary arched portions is arranged at the linear portion of the D-shaped outline.

13. The device of claim 11, wherein at least one the first pair of complementary arched portions is arranged at the curved portions of the D-shaped outline, and at least one of the second pair of complementary arched portions is arranged at the linear portion of the D-shaped outline.

14. The device of claim 3, further comprising a sealing member forming an impermeable surface coupled to at least one of the anchoring assemblies.

15. The device of claim 13, wherein the sealing member is a sheath, preferably a textile sheath, coupled to at least one of the anchoring assemblies.

16. The device of claim 13, wherein the sealing member extends to cover the extensions.

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